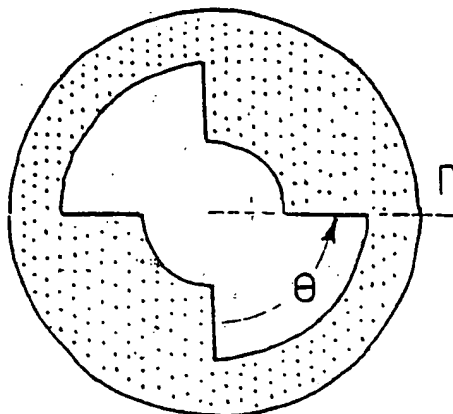




## INTERNATIONAL APPLICATION PUBLISHED UNDER THE PATENT COOPERATION TREATY (PCT)

<b>(51) International Patent Classification <sup>5</sup> :</b>  <b>A61F 9/00</b>	<b>A1</b>	<b>(11) International Publication Number:</b> <b>WO 91/11</b>  <b>(43) International Publication Date:</b> 8 August 1991 (08.0
<b>(21) International Application Number:</b> PCT/BE91/00007 <b>(22) International Filing Date:</b> 1 February 1991 (01.02.91)  <b>(30) Priority data:</b> 9000121 1 February 1990 (01.02.90) BE  <b>(71) Applicant (for all designated States except US):</b> BUCHMANN OPTICAL ENGINEERING N.V. [BE/BE]; Roozendaalstraat 14, B-8900 Ieper (BE).  <b>(72) Inventors; and</b> <b>(75) Inventors/Applicants (for US only) :</b> DIERICK, Hans, Gerard, Hugo [BE/BE]; Prieelstraat 39, B-2610 Wilrijk-Antwerpen (BE). MISSOTTEN, Luc [BE/BE]; Leo Dartelaan 12, B-3030 Heverlee (BE). SIMKENS, Peter, Eduard, Paulina [BE/BE]; Hof ter Eikenlaan 18, B-3009 Winksele-Herent (BE).		<b>(74) Agent:</b> HOIJTINK, Reinoud; Octrooibureau Arnol Siedsma, Hamoiriaan 21A, B-1180 Brussel (BE).  <b>(81) Designated States:</b> AT (European patent), BE (European patent), CH (European patent), DE (European patent), DK (European patent), ES (European patent), FR (European patent), GB (European patent), GR (European patent), IT (European patent), LU (European patent), NL (European patent), SE (European patent), US.  <b>Published</b> <i>With international search report.</i> <i>Before the expiration of the time limit for amending claims and to be republished in the event of the receipt of amendments.</i> <i>In English translation (filed in Dutch).</i>

**(54) Title:** DEVICE, MASK AND METHOD FOR ADAPTING THE CORNEAL SURFACE OF AN EYE

**(57) Abstract**

The present invention relates to a laser system and device for remodelling the anterior surface of the cornea. These are constructed from a laser source suitable for photoablation and preferably having uniform flux density distribution such as can be generated and controlled by a laser beam homogenizer (3) and monitor (5) respectively, and a laser beam characterizing system consisting of a mask rotator and a mask translator and a series of associated non-erodible masks (7), one of which is fitted at a certain time per correction in the mask rotator or translator, and wherein this mask has one or more windows with a well defined profile corresponding with a determined symmetrical profile change on the cornea. This remodelling has for its objective to correct optical disorders of the eye. This invention provides a new method and device for performing the remodelling more accurately and more stably in time. Characteristic here is that the above mentioned masks with window(s) have a central portion, the shape of which corresponds in mathematical manner with the topographical change of the optical zone of the cornea, and a peripheral portion, the shape of which corresponds in mathematical manner with the topographical change of a surrounding stabilization zone in accordance with the biodynamic properties of the corneal layers. This stabilization zone, where the remodelled surface gradually transposes into the original cornea surface, is required for the stability of the curvature correction in the central optical zone.

**FOR THE PURPOSES OF INFORMATION ONLY**

Codes used to identify States party to the PCT on the front pages of pamphlets publishing international applications under the PCT.

AT	Austria	ES	Spain	MG	Madagascar
AU	Australia	FI	Finland	ML	Mali
BB	Barbados	FR	France	MN	Mongolia
BE	Belgium	GA	Gabon	MR	Mauritania
BF	Burkina Faso	GB	United Kingdom	MW	Malawi
BG	Bulgaria	GN	Guinea	NL	Netherlands
BJ	Benin	GR	Greece	NO	Norway
BR	Brazil	HU	Hungary	PL	Poland
CA	Canada	IT	Italy	RO	Romania
CF	Central African Republic	JP	Japan	SD	Sudan
CG	Congo	KP	Democratic People's Republic of Korea	SE	Sweden
CH	Switzerland	KR	Republic of Korea	SN	Senegal
CI	Côte d'Ivoire	LI	Liechtenstein	SU	Soviet Union
CM	Cameroon	LK	Sri Lanka	TD	Chad
CS	Czechoslovakia	LU	Luxembourg	TG	Togo
DE	Germany	MC	Monaco	US	United States of America
DK	Denmark				

# DEVICE, MASK AND METHOD FOR ADAPTING THE CORNEAL SURFACE OF AN EYE

---

The present invention relates to a device, masks and a method for adapting the corneal surface of an eye.

## Background of the invention

5

Refractive surgery is a field of intense research in ophthalmology, the objective being to correct in a surgical manner frequently occurring sight disorders or ametropias such as myopia (short-sightedness), hyperopia (long-sighted-  
10 ness), astigmatism and combinations of the above, in order to replace spectacles or contact lenses.

The invention relates to that branch of refractive surgery which attempts to correct the above mentioned defects by means of a suitable laser device which removes  
15 tissue from the front of the corneal stroma by controlled volumetric ablation, whereby this surface is remodelled in order to improve the optical properties of the eye. This method of refractive surgery is called "photorefractive keratectomy" or "laser-refractive Keratoplasty" and consists  
20 of "grinding" or "remodelling" the cornea by means of laser photoablation.

Different methods and devices for ophthalmic laser surgery are described in the European patent applications EP-A-0151869, EP-A-0247260, EP-A-0207648, EP-A-0209902.  
25 Other systems for surface remodelling are described in the European patent applications EP-A-0280414, EP-A-0274205, EP-A-0225913 and EP-A-0261193.

These known techniques are based on ultraviolet radiation preferably having a wavelength of 193 nanometers  
30 such as is provided for example by a pulsed excimer laser operating on argon fluoride.

At 193 nanometers the photons have sufficient energy (6.4 eV) to break covalent bondings in molecules.

The effect can best be compared macroscopically with an "evaporation" of the molecules, called photoablation, which takes place almost without damage to the surrounding tissues (figure 5). Only molecules directly exposed to the radiation are ablated. The effect amounts to an exact and controllable removal of tissue. With a pulsed excimer laser on ArF for instance, between 0.1 and 1 micrometer ( $\mu$ ) can be ablated per shot or laser pulse.

A photorefractive operation may proceed as follows:  
the refraction of the cornea and lens, which together focus the light on the retina, is examined; the curvature of the cornea in the different meridians is determined with a keratometer; the required curvature of the cornea is computed in the different meridians so that the light focuses on the retina; the local thickness of the layer of tissue for removal in order to obtain this required curvature is computed. As fig. 1 shows, short-sightedness is corrected by flattening the cornea curvature and long-sightedness (fig. 2) by enlarging the cornea curvature. Astigmatism requires the reduction or increase of the radius of curvature in one meridian (fig. 3 and 4). The outer epithelial layer of approximately 50 micrometer thickness is carefully removed for instance with a No. 57 "hockeystick" Beaver knife.

The laser needs approximately 30 seconds to grind the cornea and the whole procedure can be carried out under local anesthesia, and optionally as out-patient treatment.

In clinical practice this technique is only acceptable if the cornea remains transparent and the induced refractive correction is predictable and stable.

A first art consists of dosing laser flux such that the desired quantity of tissue is removed to change the curvature as indicated in the figures 1, 2, 3 and 4.

Suggested in the European patent application EP-A-0151869 is the performing of a controlled photoablation of the cornea using a scanning movement over the cornea with a beam of an excimer laser.

In European patent application EP-A-0257836 the cornea curvature correction is achieved by exposing the cornea to a sequence of mask openings of differing, though related, surface area, optionally assembled on a rotating disc, wherein the cumulative effect is to expose particular zones in relation to others such that the desired net cornea curvature results, either with or without a transition ring around the operative zone to stimulate re-growth of the epithelium.

10 It is suggested in EP-A-0261193 to characterize the laser beam by an erodible mask, also called a "phantom lens" or by a mask of a material having differing transmission characteristics over the shielded zone and with a predetermined resistance profile for the laser beam.

15 Proposed in EP-A-0207648 is to achieve the remodelling effect by a controlled change in the size of the projected laser spot and to use this either through an indexable mask or mirror in the form of a plate with a collection of round or annular openings of differing diameter. Proposed in EP-A-0257836 as an alternative to the central opaque spot at the annular opening is an openable, reflective umbrella.

It is proposed in various patents to vary the size of the laser beam through an iris diaphragm, the central aperture of which, like a photographic diaphragm, can be made larger or smaller.

Proposed in EP-A-0224322 is the varying of the shape and size of the exposed zone by means of an optical system with a "beam-shaping opening or stop", and axially movable on a converging or diverging portion of the laser beam.

30 In the article by Prof. L. Missotten, "Experimental Laser Keratomileusis" (co-authors R. Boving, G. Francois and Dr. C. Coutteel M.D.; published in no. 220 of Bulletin de la Société Belge d'Ophtalmologie; p.103-120, 1987) it is proposed to modulate a uniform bundle of ultraviolet light of an excimer according to the following principle: if it wished (fig. 6) to erode by photoablation a circular symmetrical profile D on a surface, this can be done by causing a mask C

with one (or more) window(s) to rotate in the beam bundle above the surface for eroding. The mask has a rotation centre coinciding with the centre of the desired circular symmetrical profile. The shape of the window (or windows) is  
5 such that for each distance  $r$  from the rotation centre the aperture  $\theta$  is directly proportional to the thickness of the tissue for removal.

In wholly analogous manner (fig. 7) an elongate profile  $F$  can be eroded in a surface using a mask  $E$  with one  
10 (or more) window(s) which is moved forward "slidingly" in the beam bundle in accordance with the lengthwise direction of the profile perpendicularly to the axis of the laser beam, and wherein the opening distance of the window along the axis of translation ( $Y$ -axis) is proportional for each  
15 distance  $x$  from the profile to the thickness of this profile for eroding at the corresponding position.

Both principles, the rotating and the sliding mask, can be applied in different ways in photorefractive surgery.

As is described in the above mentioned publication, a  
20 spherically more negative lens can be ground on a convex surface by means of a mask with a window whereof the aperture is maximal in the centre and which gradually decreases towards the edge of the optical zone, where it reaches zero.

25 This mask could be used to give the cornea a flatter curvature (myopia correction), but the corneal tissues undergo a recovery process after photoablation. The epithelium may exhibit a hyperplasia (fig. 8) and the stroma forms new connective tissue under the epithelium. Both these  
30 phenomena change the curvature and the refraction of the anterior surface in a manner difficult to predict. The most important optically refractive surface is namely the air (refractive index 1)-tear film (refractive index 1.33) transition and not the epithelium-stroma transition.

35 Analogously, a spherically more positive lens can be ground on a convex surface by means of a mask with a window whereof the aperture is minimal in the centre and which

gradually increases towards the edge of the optical zone, where the aperture is maximal.

Such a mask can be used to grind on the cornea a zone with a smaller radius of curvature. Resulting however on the surface of the cornea is an abrupt denivelation on the edge of the ground zone. The hyperplasia of the epithelium (fig. 9) and the deposition of newly formed connective tissue on this place reduce the optical effect of the curvature correction in a manner difficult to predict, as explained above. The same problem arises if it is wished to grind a cylindrically more positive lens on a convex surface with a "sliding" mask. This mask is subjected to a translation and the zone for ablation is restricted by a second mask to a circular zone centrally on the cornea. Here also an abrupt denivelation is created whereby due to the recovery process of the corneal layers a part of the optical correction is abolished.

Experiments on rabbit eyes demonstrate that the principle of a rotating or sliding mask as described in the above mentioned article, is usable for remodelling a corneal surface. The corrections obtained are not however stable in time.

The laser normally removes no more than 50 micron, roughly 10% of the total thickness of the cornea (the Bowman layer and the surface layers of the stroma).

The eye must remain covered for several days to give the epithelium the opportunity to grow over the naked, remodelled stroma surface, and to heal. The fibroblasts in the stroma react to a keratectomy by producing collagen under the epithelium. This can be greatly inhibited by local administering of corticosteroids. (Corneal repair following Keratectomy; S. Tuft et al, Investigative Ophthalmology and Visual Science, Vol. 30, No. 8, August 1989). In order to stabilize the optical correction in the post-operative period local administering of steroids is a first important step.

The overlying epithelium consists on the other hand of very strongly interconnected cells, firmly joined to each

other by desmosomes. The hyperplasia of the corneal epithelium is less easily influenced by medication. However, the contour of the stroma has an influence on the hyperplasia of the epithelium.

5 This can be explained by a property of the epithelium comparable to the surface tension of liquids: the surface layer of the epithelium has a tendency to contract so that the total outer surface area of the epithelium remains as small as possible.

10 Where liquid molecules are held together by cohesion forces, the surface epithelium cells are held together by so-called "zonulae occludentes" or "tight-junctions". We could call this property the "slow surface tension" of the epithelium, because the effect thereof only becomes manifest  
15 after some time. The typical change of shape that an epithelial cell undergoes during its migration from the basal cell layer to the surface layer can also partly be explained by the fact that the surface cells exert a force on each other via their zonulae occludentes (drawing on p.84  
20 of Histology of the Human Eye by Hogan MJ, Alvarado JA, Weddell JE: published by W.B. Saunders Company, West Washington Square, Philadelphia PA 19105).

This so-called "slow surface tension" is a biodynamic property of the epithelium which is both favourable and  
25 unfavourable for photorefractive surgery: the epithelium covers the irregularities and provides a smooth optically refractive surface. The advantage is that the surface of the cornea does not have to be ground with the precision of a lens. The epithelium in any case grows quickly over small  
30 bumps and cavities.

Larger bumps and level differences are however also evened out by this epithelium, such as for example the sharp discontinuity at the edge between the ablated and not ablated area during remodelling to a spherically more  
35 positive lens (fig. 8). Such a discontinuity somewhat delays, but does not prevent, the regrowth of the epithelium over the operated zone. After healing even a hyperplasia of the epithelium can be expected. This reduces the optical



effect of the curvature correction in a manner difficult to predict. Ultimately, the most important optically refractive surface is the air-tear film transition and not the epithelium-stroma transition.

5 Another example is the Frensel type optical contour on the anterior surface of the cornea as already proposed in EP-A-0151869. For the same reasons this Frensel lens on a human cornea does not have the optical effect of a Frensel lens such as they are used in optics.

10

Short description of the invention

The present invention provides a device according to claim 1.

15 Preferred embodiments of the device according to the invention are characterized in the dependent claims.

The present invention further provides a mask and method for adapting the corneal surface of an eye as described in claims 7 and 9.

20 Further features, advantages and details of the present inventions will become apparent in the light of the following description with reference to the figures:

Figures 1 and 2 show how a profile of a cornea, as if it were an inert surface, must be modified to correct short-sightedness and long-sightedness respectively.

Figures 3 and 4 show how a profile of a cornea, as if it were an inert surface, must be modified to correct a stigmatism.

Figure 5 shows how a (static) mask A can characterize a beam for controlled ablation of a determined volume of tissue B.

Figure 6 shows a (rotation) mask C and a similarly circular symmetrical profile D which can be eroded by "illuminating" the rotating mask C with a homogeneous laser beam.

Figure 7 shows a (translation) mask E and a similarly elongate profile F which can be eroded by "illuminating" the sliding mask E with a homogeneous laser beam.

Figures 8 and 9 show how a hyperplasia of the epithelium can partly compensate a curvature correction.

Figure 10 shows the laser system which can consist of a laser device 1 which excites the radiation 2, a homogenizer 3 which brings about a homogeneous flux density distribution, a beam divider 4 which feeds a laser beam monitor 5 for measuring the flux density distribution, and a mask rotator or mask translator 6 with mask 7. The whole can be held in an envelope 8 with dry nitrogen. This nitrogen allows unobstructed passage of the UV radiation and prevents the formation of ozone which has an adverse affect on the laser beam.

Figures 11 and 12 show two possible arrangements of the rotating or sliding mask.

Figures 13 and 14 show a profile, a projection and a top view of the cornea with an optical zone and stabilization zone for correction of short-sightedness.

Figure 15 shows an example of a (rotation) mask suitable for myopia correction.

Figures 16 and 17 show a profile, a projection and a top view of optical zone and stabilization zone for correction of long-sightedness.

Figures 18 and 19 show two possible forms of masks suitable for hyperopia correction.

Figures 20 and 21 show a (rotation) mask suitable for correction of hyperopia with astigmatism and the angular speed of this mask as a function of the rotation position relative to the axis of the astigmatism.

Figures 22 and 23 show a profile, a projection and a top view of optical zone and stabilization zone in the case of astigmatism and correction by making flatter one meridian with stabilization zone.

Figures 24 and 25 show the form of a (translation) mask suitable for the correction of astigmatism by flattening of one meridian with a well defined translation relative to the cornea.

Figures 26 and 27 show a profile, a projection and a top view of optical zone and stabilization zone in the case

of astigmatism and correction by making one meridian with stabilization zone more curved.

Figures 28 and 29 show a form of a (translation) mask suitable for correction of astigmatism by making more curved one meridian with a well defined translation relative to the cornea.

The entirety of mask in the mask rotator or in the translator can be placed at different distances from the eye, wherein one of the two following possibilities is preferred.

According to the first configuration, the mask rotator (or translator) is situated (fig. 11) on the axis of the laser beam at for instance 20 cm from the eye of the patient, wherein the laser beam projects the mask profile onto the eye and wherein the eye is localized in the beam bundle and mechanically fixed or is fixed by a conscious effort of the patient who fixes his gaze (and therefore his eye) on a particular point in space so that the optical axis coincides with the axis of the beam bundle.

According to the second configuration (fig. 12) the mask rotator or translator is fixed on the cornea or on the eye and centered on the optical axis of this eye. Fixation can take place with a suction ring or in other conventional manner.

The mask rotator is simpler of construction if it has to be placed in the beam bundle at some distance from the eye, while in the second method it is built into a device that is placed on the eye. In this latter embodiment the mechanism is finer and lighter and ventilation of the corneal surface during the procedure is slightly more difficult. Ventilation of the corneal surface appears to be useful for removal of debris and ablation products.

Each (remodelled) cornea surface and also the change in topography or the volume for ablation can be described by one or more quadratic equations.

Taking into account the biodynamic properties of the epithelium in order to give an increasingly more stable character to the curvature correction results in a sometimes

complex topographical correction which preferably satisfies the following boundary conditions:

- the function which describes the contour of the optical zone must correspond with that of the desired spherical or spherical-cylindrical surface.

- the first derivative of the functions describing the contour of the remodelled surface consisting of optical and stabilization zone and the edge of the unmodified surface must be a continuous variable.

- the whole correction must fall within the zone of the corneal surface of the patient.

- within the limits set by the above described boundary conditions the curvature ( $1/\text{radius of curvature}$ ) must be minimal at each distance  $r$  from the optical centre.

- several arbitrary boundary conditions are the minimum diameter of the optical zone and the maximum cornea volume for ablation (the maximal ablation depth).

As example in the illustrations we selected an optical zone of a minimum 4 mm diameter and a stabilization zone of a maximum 8 mm diameter. The ideal ratios may however differ herefrom.

Additional limitations may further be imposed by the laser device and the eventual mask rotator or the cornea.

Since in preference for each distance  $r$  (or  $x$ ) from the rotation centre (or the translation axis), the aperture  $\theta$  (or the opening distance  $y$ ) is proportional to the depth of the tissue for removal, these functions can be converted into a correspondingly rotatable and/or translatable (or sliding) mask.

It can be of importance to make the global surface area of a window maximal to make the most efficient possible use of the laser beam.

For each type of ametropia the present invention provides a specific laser beam characterizing system which provides an optical zone and a well defined stabilization zone and whereof six embodiments are described below.

The masks in question are preferably manufactured from a thin sheet of non-eroding material such as inox or

brass and the windows are cut out in a mathematically exact manner by one of the modern micro-processing methods such as cutting with the YAG-laser or wire spark erosion. They are so designed that they can be rapidly placed into and removed  
5 from the rotator.

In a photorefractive procedure using rotator or translator the mask is returned after one or more full revolutions to its original position when correcting a hyperopia or a myopia, or, in the case of astigmatism  
10 correction, it has covered a well defined trajectory one or more times.

In the correction of myopia the profile consists of a central optical zone with the desired radius of curvature and an annular stabilization zone with an intermediate  
15 radius of curvature (fig. 13 and 14). The corresponding mask, an example of which is shown in fig. 15, is a first embodiment of the present invention. The portion of the window inside the dashed line serves to characterize the optical zone; the portion outside the dashed line  
20 corresponds with the stabilization zone. Characteristic here is that the stabilization zone is comparatively narrow compared to the optical zone. Many other embodiments are possible, but they comply with the same general formula. The hyperplasia of the epithelium centrally in the optical zone  
25 is restricted to a minimum with this mask.

In the correction of hyperopia as in fig. 2, the remodelled surface can be made to transpose into the original surface in an annular stabilization zone. Taking into account the biodynamic properties of the epithelium, a  
30 profile as shown in fig. 16 is to be preferred. This profile satisfies the above described boundary conditions. In a top view of the cornea (fig. 17) three zones can be distinguished: the central circle of the optical corrected zone, an annular stabilization zone and a rim of the  
35 original cornea surface. In the stabilization zone the corrected surface merges gradually and in specific manner into the original surface. The ratio of the radius of the optical zone to that of the stabilization zone (here 1/2)

can be further optimized depending on the intended correction.

The corresponding (rotation) mask, which is a second realization of the present invention, has a very specific form: a first design (fig. 18) has two windows and two spokes. A second design (fig. 19) has three windows and three spokes. The portion of the window inside the dashed line serves to characterize the optical zone; the portion outside the dashed line corresponds with the stabilization zone.

10 Characteristic here is that the maximum thickness for ablation and the maximum aperture lie outside the optical zone in the stabilization zone. Many other embodiments are possible but they all comply with the equivalent formula. The rotation speed and the number of revolutions are well

15 defined and a function of the maximum depth for ablation, i.e. of the extent of the optical correction.

In a third embodiment this invention proposes a method and device for correction of a hyperopia in combination with a slight astigmatism. It is a variant of

20 the second aspect of this invention, i.e. it comprises a mask the shape of which complies with the general description for hyperopia correction and is characterized by the fact that there are only two windows, with a symmetry around the X-axis and the Y-axis and such that one window

25 can be written in one quadrant of the mask. The mask is subjected to a rotation in two phases: in a first phase the hyperopia is corrected, in a second phase the astigmatism. The angular speed is constant in the first phase and displays a variation per revolution in the second phase as

30 according to fig. 21: such that in this second phase the exposure period of the cornea zone perpendicular to the axis of the astigmatism is greater than that of the cornea zone in the axis of the astigmatism. This generates a cylindrical component in the remodelled cornea and permits the use of

35 the same mask for both types of correction.

For a stable correction of astigmatism by flattening one meridian (as in fig. 3), this invention proposes to correct the curvature in the said meridian as in fig. 22

with a narrow stabilization zone and, in the meridian perpendicular thereto - above and below -, to have the remodelled surface surrounded by a stabilization zone bounded by the shape of the window and the limited translation and characterized by the fact that the window does not pass thereover (fig. 23 and 24) along its whole maximum opening distance (in the translation axis).

The meridian in the translation axis preserves the same radius of curvature in the region where the window passes over its whole height (opening distance) because a peel of equal thickness is ablated over this region. In the region where the window does not pass over its whole height the ablated peel becomes increasingly thinner and the ablated surface in the meridian of translation merges gradually into the original surface having the same radius of curvature (fig. 22).

The corresponding (translation) mask, which is a fourth embodiment of the present invention, has a specific shape (fig. 25), characterized by a symmetry about the X-axis and the Y-axis and bounded by two paraboloids. It is subjected to a well defined translation movement (fig. 24) with well defined starting and finishing points relative to the cornea and with a translation speed which is a function of the maximum depth for ablation. Characteristic here is that in its starting and finishing positions the window falls completely outside the optical zone.

There are possibilities other than that shown in fig. 25. Resulting from laser photoablation with characterizing of the laser beam in this manner is a corneal topography which is flattened in one meridian, with this meridian having a (narrow) stabilization zone and the meridian of translation having an unchanged radius of curvature in the optical zone due to a uniform ablation with a specific stabilization zone as in fig. 23.

The translation axis is parallel to the axis of a negative cylindrical glass necessary for correction of the eye.

For a stable correction of astigmatism by making one meridian more curved (fig. 4) the invention proposes to correct the curvature in the said meridian as in fig. 26 and to have the remodelled surface surrounded by a butterfly-shaped stabilization zone bounded by the shape of the window (fig. 29) and the limited translation. The shape of the window ensures that the curvature correction both in the corrected meridian and in the direction perpendicular thereto extends slopingly outward in accordance with the biodynamic properties of the cornea. Characteristic here also is that the maximum thickness for ablation and the maximum opening distance of the (translation) mask lie outside the optical zone in the stabilization zone. The meridian in the translation axis centrally in the optical zone preserves the same radius of curvature because nothing is ablated over this region.

The corresponding (translation) mask, the example of which in fig. 29 is a fifth realization of the present invention, has a specific shape characterized by a symmetry about the X-axis and the Y-axis and is subjected to a well defined translation movement (fig. 28) with well defined starting and finishing points relative to the cornea and with a translation speed which is a function of the maximum depth for ablation. Characteristic here is that in its starting and finishing positions the window falls completely outside the optical zone.

Resulting from laser photoablation with characterisation of the laser beam in this manner is a corneal topography with an increased curvature in one meridian, while the meridian in the axis of translation remains unchanged.

The translation axis is parallel to the axis of a positive cylindrical glass necessary for correction of the eye.

It is self-evident that the mixed ametropias can be corrected by a succession of various of the above described methods and devices. The experimental results have as yet to



confirm the correct ratios of optical zone and stabilization zone in the different types of correction.

In a preferred arrangement the flux density distribution of the laser beam is made homogeneous by a laser beam homogenizer, some types of which are commercially available, such as from the firm Exitech, Long Hanborough, Oxford, UK, and this homogenizing process is continually controlled by a laser beam monitor, likewise available from the same firm. In the applications described above use is made each time of an excimer laser beam, the diameter of which is preferably sufficiently large to simultaneously illuminate the whole mask with all windows and the optical zone and stabilization zone on the cornea.

A first and main advantage is that with a single, relatively simple device a central and a peripheral part of the laser beam is characterized with a view to stable correction of an ametropia by a topographical change that is a combination of a curvature correction in the optical zone and a curvature adaptation in the so-called stabilization zone, taking into account the biodynamic properties of the epithelium.

A second and particularly advantageous property of these masks is that a greater or smaller dioptric correction can be obtained by causing the illumination period or number of pulses on the same mask to increase or decrease: the maximum ablation depth hereby increases or decreases, ablation depth being the product of the number of pulses multiplied by the ablation depth per shot or laser pulse.

A third advantage is that the shape of a window can be made very precisely and mathematically exact with the present micro-processing methods and that this shape is fixed and much more stable than for instance a variable transmission characteristic of a mask, of which it is known that it can change under the influence of the laser beam. The effect of the shape of the window on the ablation depth is easier to predict than for instance the effect on the ablation of an erodible "phantom" lens.

A fourth advantage is that the largest discontinuities that are formed on the surface are the size of the ablation thickness of one shot, whereby the remodelled surface is smoother and does not display any 5 concentric stages as in some other systems.

A fifth advantage is that it is a comparatively inexpensive device because the masks can be re-used.

## CLAIMS

1. Device for adapting an anterior corneal surface of an eye, comprising:
  - a laser for generating a laser beam;
  - a homogenizer for homogenizing the laser beam5 coming from the laser with substantially circular symmetrical flux density change;
  - at least one mask arranged between the eye and the homogenizer; and
  - a member for causing the mask to translate and/or10 rotate, wherein the translation and/or rotation movement and the shape of the mask are adapted to one another such that in radial direction of the anterior corneal surface a transition zone is provided in which the adapted central portion of the anterior corneal surface gradually merges
- 15 into the original, non-modified corneal surface.
2. Device as claimed in claim 1, wherein the mask comprises a number of windows in a plate of a non-erodible material that has absolutely no transmission for the laser beam used.
- 20 3. Device as claimed in claim 1 or 2, wherein the mask is placed at a short distance, for instance a few millimetres from the eye, above the cornea.
4. Device as claimed in claim 1 or 2, wherein the mask is placed at a distance of approximately 20 cm above
- 25 the eye.
5. Device as claimed in any of the claims 1-4, wherein the mask is rotated and wherein the mask has a rotation-symmetrical form with preferably two lobe-shaped windows.
- 30 6. Device as claimed in any of the claims 1-5, wherein the mask has butterfly-shaped windows.
7. Mask for use in the device as claimed in any of the foregoing claims, wherein the geometrical form of the windows roughly corresponds with that of the figures.

8. Mask for use in the device as claimed in any of the foregoing claims, provided with a first central window portion for the central portion of the cornea and a peripheral window portion for the transition zone.

5        9. Method for adapting the anterior corneal surface of an eye, wherein a new curvature is given to a central portion of the cornea and wherein for stabilizing this new curvature a stabilization ring is arranged around the central portion in the anterior cornea using the same laser  
10 beam with which the new curvature is arranged so that there results a stable transition to the portion of the cornea not treated with a laser bundle.

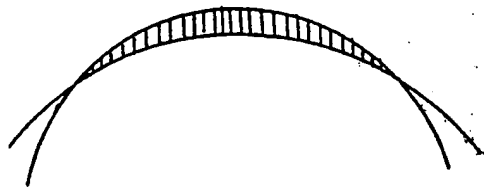


FIG. 1

1/5



FIG. 2

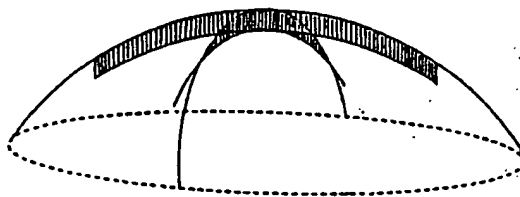


FIG. 3

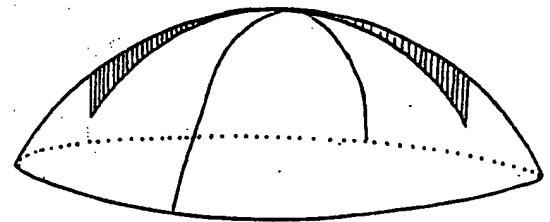


FIG. 4

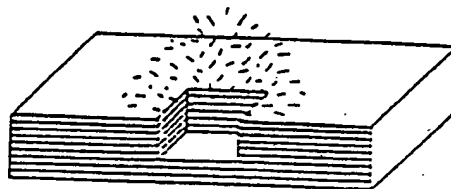
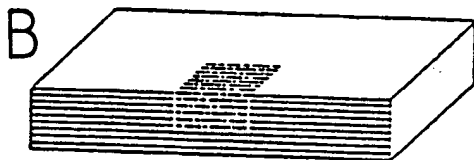
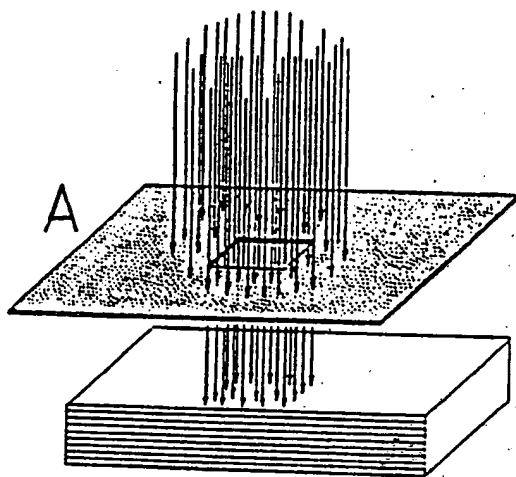


FIG. 5

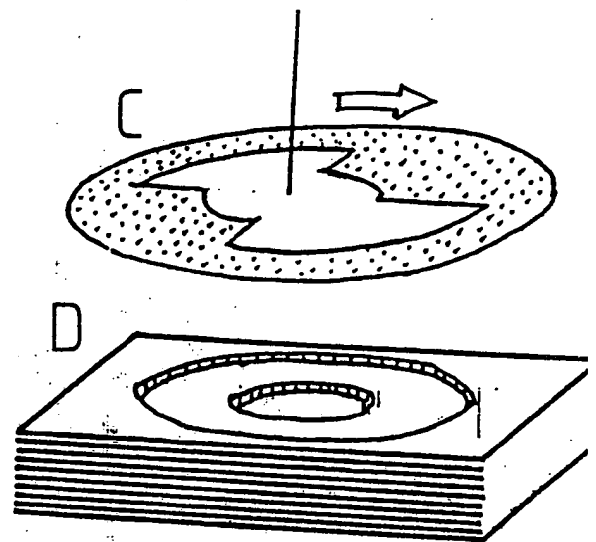
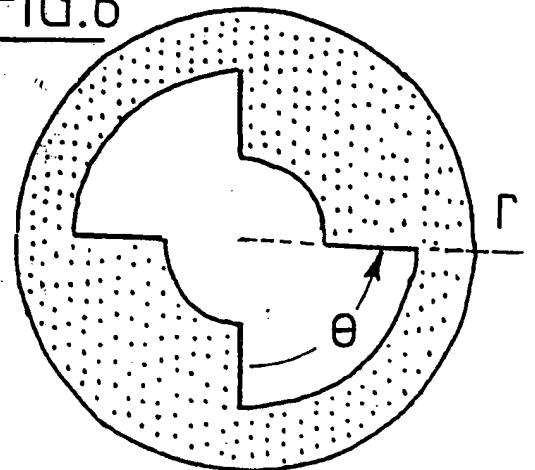


FIG. 6



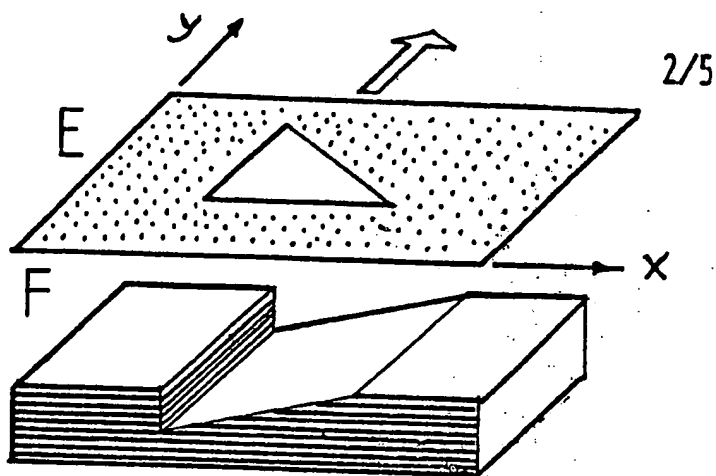


FIG. 7

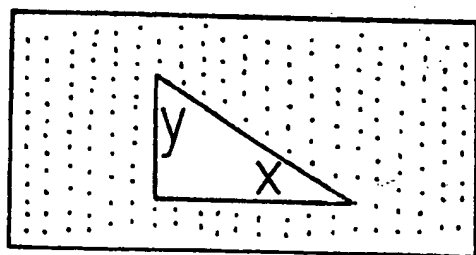


FIG. 13

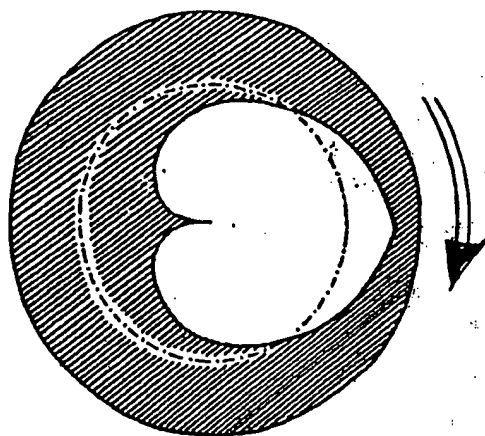
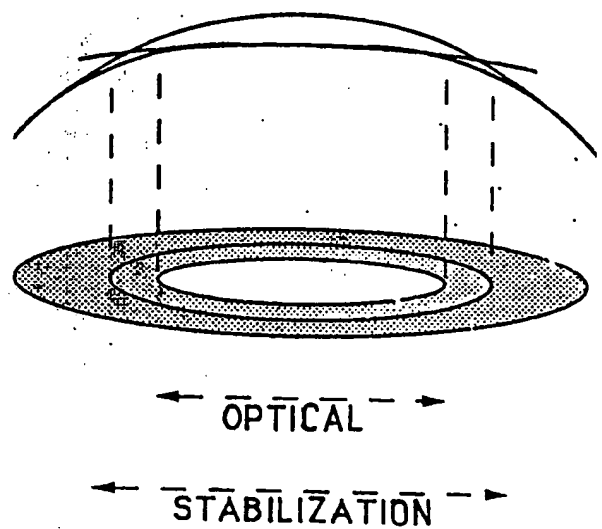


FIG. 15

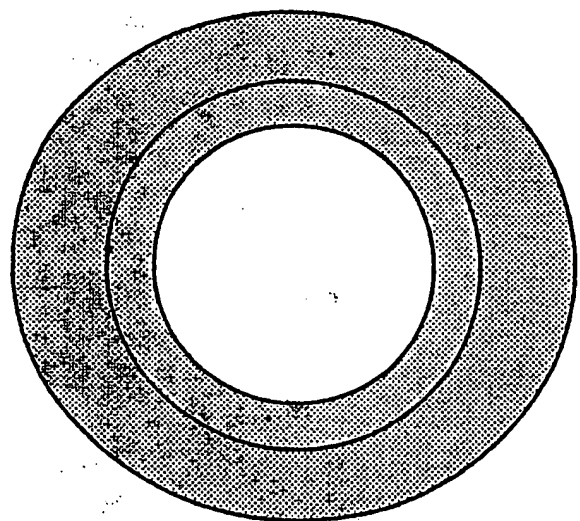
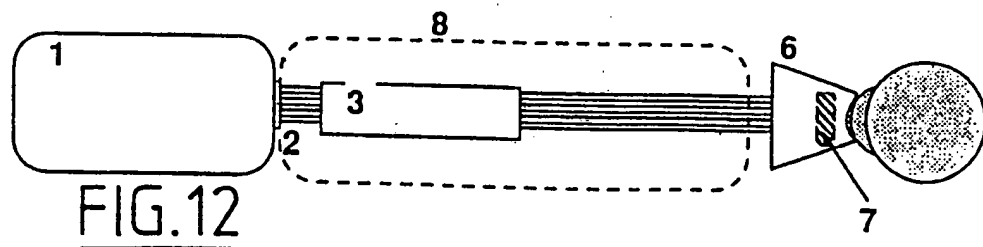
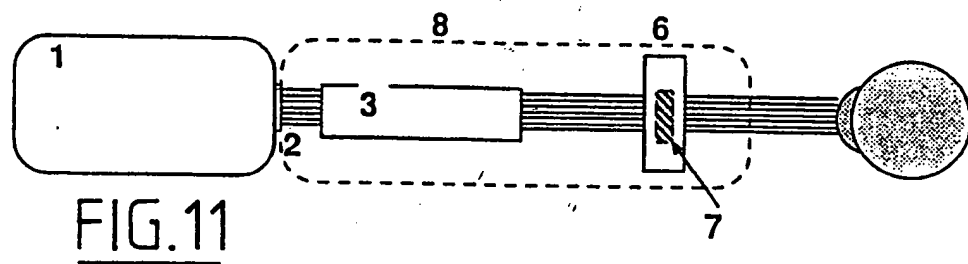
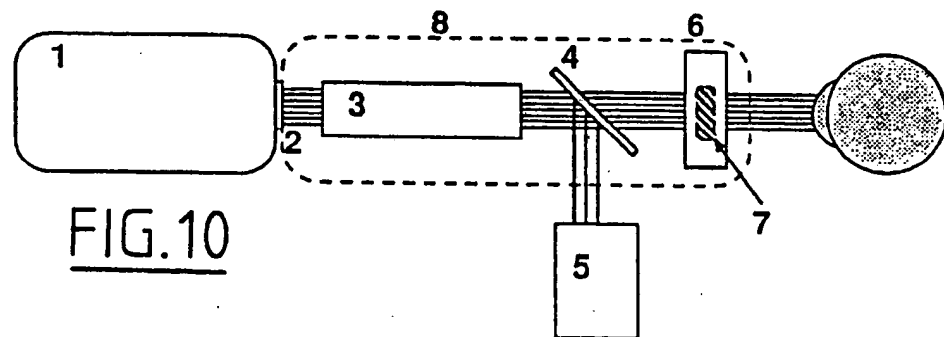
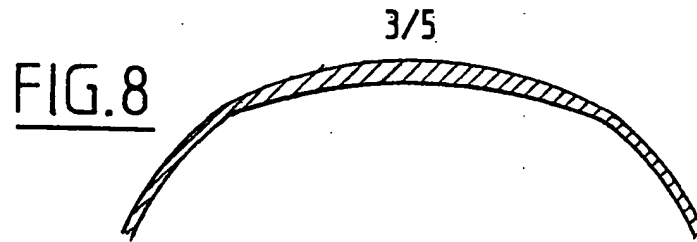
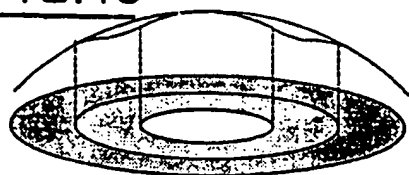


FIG. 14



4/5

FIG.16



OPTICAL  
STABILIZATION

FIG.17

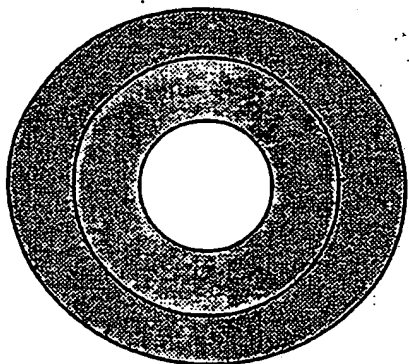


FIG.18

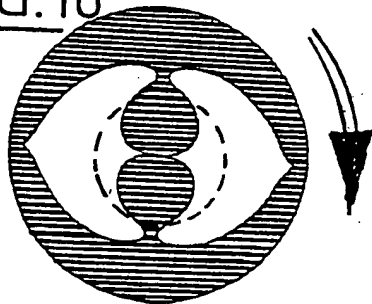


FIG.19

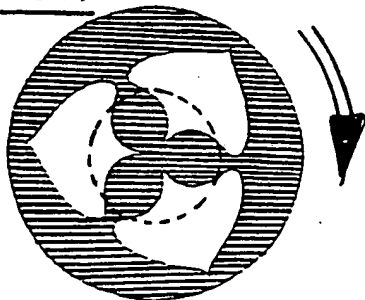


FIG.20

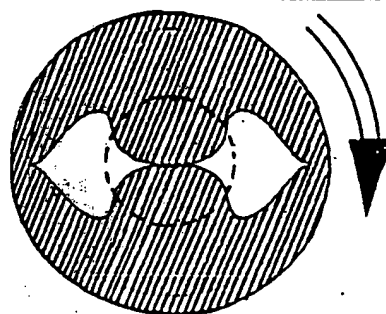
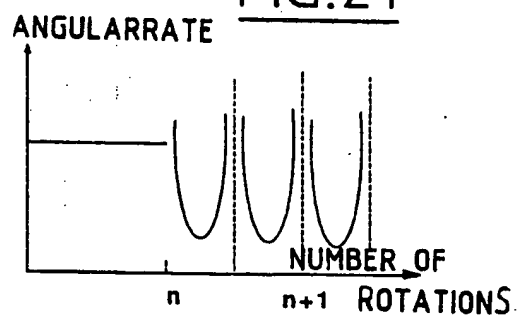


FIG.21





5/5

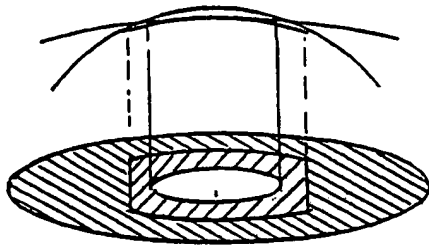


FIG. 22 OPTICAL  
STABILIZATION

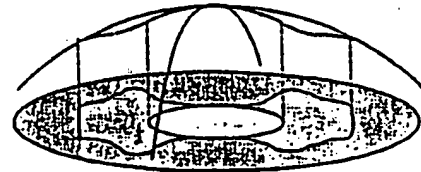


FIG. 26 OPTICAL  
STABILIZATION

FIG. 23

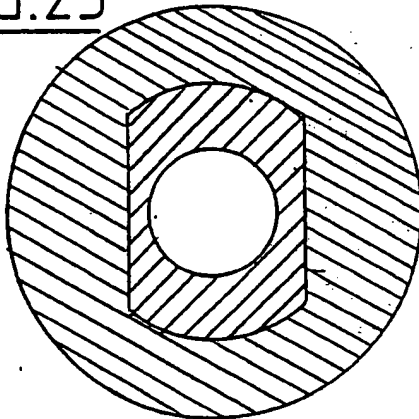


FIG. 27

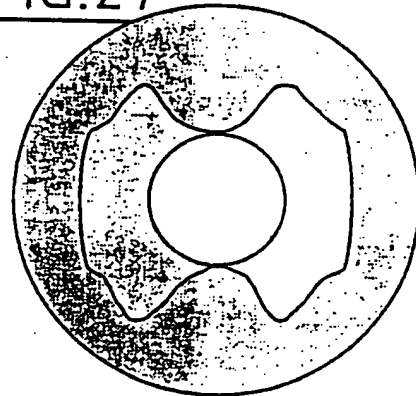


FIG. 24

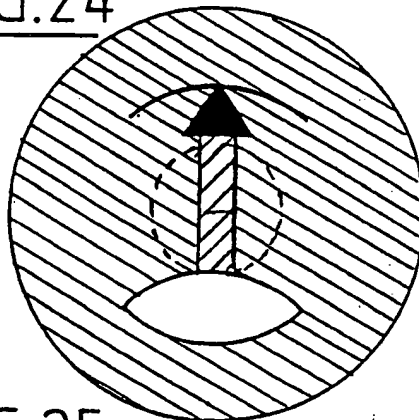


FIG. 28

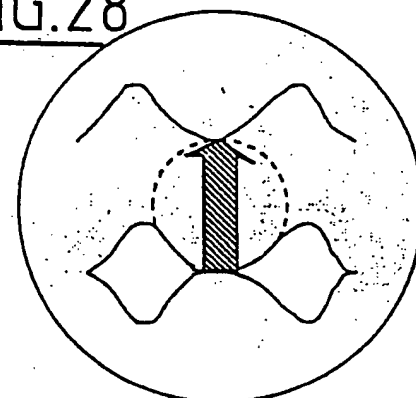


FIG. 25

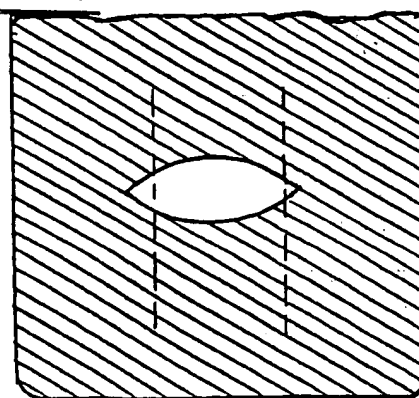
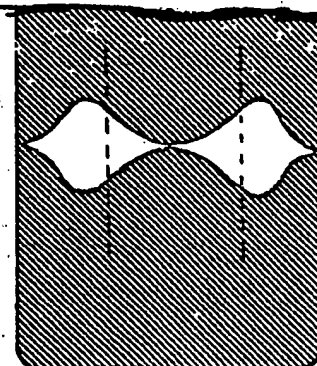


FIG. 29



# INTERNATIONAL SEARCH REPORT

International Application No

PCT/BE 91/00007

## I. CLASSIFICATION OF SUBJECT MATTER (If several classification symbols apply, indicate all) <sup>4</sup>

According to International Patent Classification (IPC) or to both National Classification and IPC

IPC<sup>5</sup>: A 61 F 9/00

## II. FIELDS SEARCHED

Minimum Documentation Searched <sup>7</sup>

Classification System

Classification Symbols

IPC<sup>5</sup>

A 61 F

Documentation Searched other than Minimum Documentation  
to the Extent that such Documents are Included in the Fields Searched <sup>8</sup>

## III. DOCUMENTS CONSIDERED TO BE RELEVANT <sup>9</sup>

Category <sup>10</sup>	Citation of Document, <sup>11</sup> with Indication, where appropriate, of the relevant passages <sup>12</sup>	Relevant to Claim No. <sup>13</sup>
X	DE, A, 3615042 (DARDENNE) 12 November 1987 see figure 1; column 11, lines 15-21; column 12, lines 44-49	1-3, 5, 6, 8
Y	--	4
Y	EP, A, 0296982 (HANNA) 28 December 1988 see figure 7; page 10, lines 61-65; figure 4; page 13, lines 48-51	4
A	--	1, 5
A	US, A, 4770172 (L'ESPERANCE) 13 September 1988 see column 3, lines 17-43	1
A	FR, A, 2633826 (MIKROKHIRURGIA GLAZA) 12 January 1990	
	-----	

<sup>10</sup> Special categories of cited documents:

"A" document defining the general state of the art which is not considered to be of particular relevance

"E" earlier document but published on or after the international filing date

"L" document which may throw doubts on priority claim(s) or which is cited to establish the publication date of another citation or other special reason (as specified)

"O" document referring to an oral disclosure, use, exhibition or other means

"P" document published prior to the international filing date but later than the priority date claimed

"T" later document published after the international filing date or priority date and not in conflict with the application but cited to understand the principle or theory underlying the invention

"X" document of particular relevance; the claimed invention cannot be considered novel or cannot be considered to involve an inventive step

"Y" document of particular relevance; the claimed invention cannot be considered to involve an inventive step when the document is combined with one or more other such documents, such combination being obvious to a person skilled in the art

"Z" document member of the same patent family

## IV. CERTIFICATION

Date of the Actual Completion of the International Search

3rd May 1991

Date of Mailing of this International Search Report

27.06.91

International Searching Authority

EUROPEAN PATENT OFFICE

Signature of Authorized Officer

*D. Haas*

Danielle van der Haas

## FURTHER INFORMATION CONTINUED FROM THE SECOND SHEET

☒ **V. OBSERVATIONS WHERE CERTAIN CLAIMS WERE FOUND <sup>incompletely</sup> UNSEARCHABLE**

This International search report has not been established in respect of certain claims under Article 17(2) (a) for the following reasons:

1. ☒ Claim numbers 9, because they relate to subject matter not required to be searched by this Authority, namely:

Pls. see Rule 39.1 (iv) - PCT:

Methods for treatment of the human or animal body by surgery or therapy, as well as diagnostic methods.

2. ☒ Claim numbers 7, because they relate to parts of the international application that do not comply with the prescribed requirements to such an extent that no meaningful international search can be carried out, specifically:

Claim 7 searched incompletely

"Claims shall not, except where absolutely necessary, rely, in respect of the technical features of the invention, on references to the description or drawings. In particular, they shall not rely on such references as: "as described in part... of the description," or "as illustrated in figure... of the drawings (Rule 6.2 (a) - PCT)

3. ☐ Claim numbers \_\_\_\_\_, because they are dependent claims and are not drafted in accordance with the second and third sentences of PCT Rule 6.4(a).

☐ **VI. OBSERVATIONS WHERE UNITY OF INVENTION IS LACKING**

This International Searching Authority found multiple inventions in this international application as follows:

1. ☐ As all required additional search fees were timely paid by the applicant, this international search report covers all searchable claims of the international application.
2. ☐ As only some of the required additional search fees were timely paid by the applicant, this international search report covers only those claims of the international application for which fees were paid, specifically claims:
3. ☐ No required additional search fees were timely paid by the applicant. Consequently, this international search report is restricted to the invention first mentioned in the claims; it is covered by claim numbers:
4. ☐ As all searchable claims could be searched without effort justifying an additional fee, the International Searching Authority did not invite payment of any additional fee.

Remark on Protest

- ☐ The additional search fees were accompanied by applicant's protest.
- ☐ No protest accompanied the payment of additional search fees.

**ANNEX TO THE INTERNATIONAL SEARCH REPORT  
ON INTERNATIONAL PATENT APPLICATION NO.**

BE 9100007

SA 43971

This annex lists the patent family members relating to the patent documents cited in the above-mentioned international search report. The members are as contained in the European Patent Office EDP file on 18/06/91  
The European Patent Office is in no way liable for these particulars which are merely given for the purpose of information.

Patent document cited in search report	Publication date	Patent family member(s)	Publication date
DE-A- 3615042	12-11-87	None	
EP-A- 0296982	28-12-88	FR-A- 2617042	30-12-88
		JP-A- 1086968	31-03-89
US-A- 4770172	13-09-88	US-A- 4665913	19-05-87
		US-A- 4798204	17-01-89
		CA-A- 1243732	25-10-88
		EP-A, B 0151869	21-08-85
		JP-A- 60119935	27-06-85
		US-A- 4773414	27-09-88
		US-A- 4732148	22-03-88
		US-A- 4718418	12-01-88
		CA-A- 1271813	17-07-90
		EP-A- 0209992	28-01-87
		JP-A- 62053650	09-03-87
		CA-A- 1259105	05-09-89
		EP-A, B 0207648	07-01-87
		US-A- 4729372	08-03-88
		EP-A- 0218427	15-04-87
		JP-A- 62101247	11-05-87
FR-A- 2633826	12-01-90	DE-A- 3922819	18-01-90
		GB-A- 2221162	31-01-90
		JP-A- 2084955	26-03-90
		US-A- 4953969	04-09-90

**This Page is Inserted by IFW Indexing and Scanning  
Operations and is not part of the Official Record**

## **BEST AVAILABLE IMAGES**

Defective images within this document are accurate representations of the original documents submitted by the applicant.

Defects in the images include but are not limited to the items checked:

- ☐ **BLACK BORDERS**
- ☐ **IMAGE CUT OFF AT TOP, BOTTOM OR SIDES**
- ☐ **FADED TEXT OR DRAWING**
- ☐ **BLURRED OR ILLEGIBLE TEXT OR DRAWING**
- ☐ **SKEWED/SLANTED IMAGES**
- ☐ **COLOR OR BLACK AND WHITE PHOTOGRAPHS**
- ☐ **GRAY SCALE DOCUMENTS**
- ☒ **LINES OR MARKS ON ORIGINAL DOCUMENT**
- ☐ **REFERENCE(S) OR EXHIBIT(S) SUBMITTED ARE POOR QUALITY**
- ☐ **OTHER:** \_\_\_\_\_

**IMAGES ARE BEST AVAILABLE COPY.**

**As rescanning these documents will not correct the image problems checked, please do not report these problems to the IFW Image Problem Mailbox.**